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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/308,607 | 05/20/1999 | YOSHIKAZU UMEZU | 34650/DBP | 6401 |

7590 10/14/2003

D BRUCE PROUT
CHRISTIE PARKER & HALE
350 WEST COLORADO BOULEVARD
SUITE 500
PASADENA, CA 91105

EXAMINER

JOYNES, ROBERT M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/14/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/308,607

Applicant(s)

UMEZU ET AL.

Examiner

Robert M. Joynes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11-15 and 18 is/are pending in the application.
- 4a) Of the above claim(s) 6-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11-15 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 16 and 17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed on July 17, 2003.

Election/Restrictions

Applicants have presented new claims 16 and 17. The new claims will not be considered because they are drawn to previously non-elected subject matter.

Applicants elected, without traverse, a composition with a drug and the process of making the composition with the drug and did not elect the composite (the filler) or the process of producing the filler. Therefore, the new claims will not be considered and the restriction is deemed final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1, 2, 5 and 11, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schumacher (DE 3835728 A1) or Reetz et al. (DE 4118752 A1) in combination with Vit et al. (US 4693986).

Schumacher teaches the production of particles from 1 to 1000 nanometers by atomizing a solution containing the ceramic material in a cold reactor to freeze the droplets, freeze drying the obtained particles and further sintering the particles (See Abstract).

Reetz teaches a method of dropping ceramic material into liquid cooling medium, freeze-drying the granule followed by sintering (See Abstract). The average particle size of the ceramic is 0.04-0.4 mm (See Abstract).

Niether Schumacher or Reetz teach the inclusion of a binder to the ceramic material.

Vit teaches ceramic particles that include a binding agent (Col. 4, lines 30-68; Col. 5, lines 1-35; Col. 6, lines 1-68). During the heating/sintering step, the binder is decomposed without leaving an unwanted residue on the ceramic material (Col. 4, lines 30-68; Col. 5, lines 1-35; Col. 6, lines 1-68). The preferred binding agents are starch, polyvinyl alcohol and polyvinyl pyrrolidone (Col. 4, lines 52-55).

The prior art does not expressly teach the exact particle size range or the exact concentration ranges for the particles formed. However, absent a clear showing of criticality or some unexpected result, the determination of particular concentrations and particle sizes is within the skill of the ordinary worker as part of the process of normal optimization.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare ceramic particles that include a binder by dropping the starting material into a low temperature medium, freeze drying the particles followed by sintering.

One of ordinary skill in the art would have been motivated to do this to provide a strong, free-flowing, structurally stable ceramic particle.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 3, 4, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schumacher (DE 3835728 A1) or Reetz et al. (DE 4118752 A1) in combination with Vit et al. (US 4693986) and Urist (US 4596574).

The teachings of Schumacher, Reetz and Vit are discussed above. These references do not expressly teach the impregnating of the ceramic particle with a drug.

Urist teaches a porous ceramic system with an active agent impregnated on the ceramic (Col. 2, lines 13-44; Col. 3, lines 45-53). The porous ceramic is comprised of physiologically acceptable, biodegradable salt, specifically a phosphate, more specifically tricalcium phosphate (Col. 2, lines 22-30). The porous ceramics are sintered to reduce their solubility (Col. 2, lines 31-38; Col. 3, lines 58-63). The active agent, bone morphogenetic protein (BMP), is then impregnated into the pores of the ceramic (Col. 3, lines 45-53).

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At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to impregnate a porous ceramic particle with a drug or active agent.

One of ordinary skill in the art would have been motivated to do this to deliver an active agent in such a way that provides better administration and minimizes inflammatory reactions to the carrier system or implant.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed July 17, 2003 have been fully considered but they are not persuasive. Applicants argue that the new limitation of the starting material being dropped into a low temperature medium from a thin tube having an inner diameter ranging from about 0.3 to 2mm distinguishes the instant claims over the prior art. This argument is found to be unpersuasive. The prior art teaches a method of atomizing a starting material into submicron particles by sending the material into a low temperature medium to freeze dry the particles followed by sintering. Applicants' introduction of the new language regarding the this tube does not overcome the prior art because implicit in the teaching of atomization of the starting material is point that the starting material had to be dropped from a tube into the low temperature medium to form the particles. This is clearly illustrated in the Gombotz (US 5019400) reference cited in the first Office Action. The illustration clearly shows the starting material is dropped/atomized through a tube into a low temperature medium. Therefore, it is implicitly taught by the cited prior

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art that the starting material is atomized or dropped into the low temperature medium through a tube. Further, the applicants have not shown any unexpected results with regard to the size of the tube. The size of the tube will be determined by the size of the particles to be prepared by the method. The prior art teaches particles whose size are within the range recited in the instant claims (new Claim 18). Therefore, applicants' arguments about the new language of the claims distinguishing the claims over the prior art are found unpersuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
October 6, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600